CLINICAL LABORATORY BULLETIN August 2007

Web page: http://health.utah.gov/lab/labimp

❖ INTRODUCING:

Merril Chipman Environmental Chem

NOTEWORTHY

✓ **Quality capillary specimens:** Clinical Laboratory Standards Institute (CLSI) document H4-A5 States "A scooping motion to collect blood and strong repetitive pressure (milking) must be avoided, as both procedures may result in hemolysis or tissue fluid contamination of the specimen." With this in mind when you select a capillary blood collection device, avoid one with an integrated scoop or channel tube. Such a device may encourage scooping. Be aware that open-ended containers with a thick rim can lead to scooping as the rim provides a barrier to capillary flow.

An article in the June 18, 2007 issue of Advance mentions two devices available from Sarstedt Inc. One product has a capillary straw to draw blood from the drop without touching the skin. They also provide a more traditional container with a thin rim that may overcome the tendency to "scoop" up the blood drops.

Ask your provider what type of new collection devices are available. Capillary specimens are so small and take so much time to collect, make certain the final sample gives accurate test results.

✓ **Lubricants may interfere with liquid based cervical cytology specimens:** The May issue of CAP Today reported the results of a Sonora-Quest Laboratories study in Tempe, AZ. The controlled study demonstrated the effect 9 commercially available lubricants could have on ThinPrep slides used for PAP smears. No ill effects on specimen cells were seen with K-Y Lubricating Jelly, Surgilube, Replens and Walgreen's Lubricating Jelly. Specimens containing FemGlide, Triad, Maxilube, Aquagel or Aquasonic resulted in unsatisfactory slides due to scant squamous cell components. The matched control slides for these specimens all contained adequate cellular components.

The article noted the few reports stating there is no effect on cytology interpretation or HPV testing when lubricants were used tested only water-soluble lubricants.

✓ **Electronic medical record:** When the laboratory report is transmitted directly to the patient's electronic chart, watch for pitfalls.

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Does the format stay the same? Is it the same when you add "canned" or free text comments?

Does the chart copy state clearly where the test was done (i.e. point of care, reference lab, another lab in the corporation)? Such information is required by CLIA.

What happens to graphs or images upon transfer? There are reports of problems in pathology result transmission as the ASCII control characters or escape sequences from legacy systems may change the chart record. For example, certain characters (alone or in combination) may be interpreted as stop or delete commands and the rest of the text may be lost.

Periodically spot check transfer results as part of your regular quality assurance checks. Test the system extensively following a computer upgrade on either end.

✓ **Diagnosis based therapy:** An article in the January 1, 2007 issue of Advance by Susan Remson, MS, MT(ASCP) related a new word for this concept "theranostics". Though not in the dictionary, you can get hundreds of hits on Google!

The concept is relatively new. First there was Herceptin treatment for breast cancer patients with over-expressed HER-2 protein. Then Erbitux or Vectibix for colorectal cancer patients with epidermal growth factor receptor (EGFR). Finally, Gleevac was used in chronic myelogenous leukemia (CML) for patients with the BCR-abl gene.

So what's new? FDA has approved Amplichip CYP450 to identify phenotypic genes in the cytochrome P450 system that can influence a patient's ability to metabolize certain antidepressants, antipsychotics and ADHD drugs. UGT1A1 gene can influence a patient's ability to break down Camptosar (colon cancer chemotherapeutic) that leads to a higher risk of side effects. And lastly, TruGene-HIV1 Genotyping Kit was approved to guide therapy selection based on genetic variations that make the HIV virus resistant to certain drugs.

Personalized medicine is on the way.

✓ **Mohs – hints for Histotechs:** Mickie Johnson, HTL(ASCP) gave useful hints for laboratories considering adding, remodeling or moving Mohs surgery in the April 23, 2007 issue of Advance. Consider the following:

1. You will need about 100 square feet to facilitate equipment placement and workflow needs.
2. Ensure you allow enough space on the sides and back of the cryostat for free air circulation through the vents. This will minimize compressor overheating.
3. It is better to exhaust excess heat outside the room than to use an air conditioner to cool recycled air.
4. Be certain the cryostat you purchase was designed ergonomically. It should have a knife holder and a horizontal clamping plate to manipulate the tissue section.
5. Good lighting is critical. A single, high intensity lamp bulb is best.
6. Use high quality, soft bristle, camelhair brushes. Quality tools = quality preparations.

The entire article is available on Advance's website at www.advanceweb.com/MLP.

✓ **Phlebotomy certification:** The Bureau of Laboratory Improvement receives frequent calls regarding phlebotomy certification and/or licensing. Utah does not have a regulation requiring either. There is a law (Utah Administrative Code – Rule R438-12) "Rules for the Authorization of Individuals Other Than Physicians, Registered Nurses, or Practical Nurses to Withdraw Blood for Alcoholic or Drug Determinations When Requested by a Peace Officer, and for Issuance of Permits to Such Individuals".

The American Society of Clinical Pathologists (ASCP) has a registry for phlebotomists. Other agencies may offer licenses or certificates for courses they give. Private clinical lab corporations or individual physician offices may require training or their own "certification" to work as a phlebotomist for them.

Bottom line – Federal CLIA regulations and Utah State Rules do **not** require a license or certification to draw blood except the state's forensic / law enforcement rule mentioned above.

✓ **Another use for D-dimer?:** Karen Titus interviewed William E. Luper, MD for the March 2007 issue of CAP Today about the use of D-dimer to determine how long clinicians should continue anticoagulation therapy for certain patients. A report from the New England Journal of Medicine concluded patients with an abnormal D-dimer one month after halting anticoagulation were more likely to develop another venous thromboembolism than those with a normal value. Maybe anticoagulation therapy duration will soon be guided by a patient's D-dimer test results.

✓ **Does your emergency first aid kit include QuikClot?:** It may in the future. The military uses this granular zeolite powder (looks like cat litter) to absorb water in the blood and cause it to clot. Another version, QuikClot ACS is a porous pouch of the agent wrapped in surgical gauze that can be packed on a wound. These products were first used on humans in Afghanistan. Civilian fire fighters and emergency medical technicians are using these products in the USA to stop severe bleeding.

✓ **Brucella or Bartonella?:** In times of biological terrorism threats, we are more sensitive to accurate bacterial identification – not just the susceptibility results. The Michigan public health laboratory had an unusual isolate from an elderly man diagnosed with endocarditis following extensive dental work. Serology tests on the patient were positive for *Brucella* IgG. However, GLC analysis of the bacterial isolate was compatible with *Bartonella henselae*. The latter identification was confirmed by CDC. This agent of cat scratch fever is rarely cultured as healthy individuals usually recover without hospitalization.

✓ **Reportable diseases - Utah:** The Utah Department of Health updated the list of reportable diseases in June 2007. The list is available at http://health.utah.gov/epi. Some diseases require immediate telephone notification (1.888.374.8824). Others can be reported within 3 working days. The report may be given to the local health department in lieu of the state.

The Utah Public Health Laboratories (UPHL) changed the list of organisms the testing lab should submit. The microbiology lab no longer needs vancomycin resistant enterococci (VRE) or methicillin resistant *Staphylococcus aureus* (MRSA). They do need toxin producing *E. coli*. You can send an organism isolate or the enrichment broth. Certain screening methods fail to differentiate between *Shigella* and toxin producing *E. coli* (such as 0157 H7). The treatment and case management is different for the different organisms.

For additional information, contact the Bureau of Microbiology at UPHL (801.584.8400).

QUOTES

"There is more to life than increasing its speed."
Mahatma Gandhi

☆ Feature ☆

Clinical Laboratory Improvement Amendments (CLIA)

Equivalent Quality Control Procedures Brochure #4

What are they and when can I use them?

(Excerpts from the brochure. Read the complete brochure at www.cms.hhs.gov/clia)

BACKGROUND

(not included)

EQUVALENT QC PROCEDURES

How many equivalent QC procedure options are there?

At this time, there are three equivalent QC procedure options. The options are based on whether the test system has an internal monitoring system and if so, whether it checks all or only some of the test system's analytic components. As further technological advances are made and additional data become available, other options may be included or existing options revised.

Is the test system I'm using eligible for an equivalent QC procedure?

To determine eligibility for an equivalent QC procedure, the laboratory must consider the following:

Test System Criteria: Whether or not the test procedure includes an extraction step, and the specialty/subspecialty of the test procedure, affect the test system's eligibility for equivalent QC procedures. Table 2 will help you to determine if a test system is eligible for equivalent QC and if so, which options might be used.

Manufacturer's Instructions: Manufacturers' test system instructions must always be followed. Therefore, if the test system instructions require testing external control materials more frequently than required by equivalent QC procedures, or testing more than two levels of external control materials, the test system is not eligible for equivalent QC.

Excluded Methods: Test systems that use molecular amplification, thin layer chromatography, or electrophoretic procedures are not currently eligible for equivalent QC procedures.

What should I consider before choosing to evaluate a test system for equivalent QC?

In general, test systems that have a history of infrequent QC failures, and that are simple to use, very stable, and routinely performed in your laboratory, are the most suitable for equivalent QC procedures. Therefore, you should take into account the following:

- *Instrumentation and reagents*—Test systems using reliable and easy-to-maintain instruments, and reagents that are stable and do not require special handling or storage are good candidates for equivalent QC procedures.

- *Technique dependence of the test method*—Test methods with few and uncomplicated procedural steps are less prone to operator error.

- *Frequency and volume of test performance*— Frequently performed tests or high volume tests are more familiar to the laboratory's testing personnel, making them less prone to operator error.

- *Frequency of control failures*—Test systems with few control failures over time are more suited for equivalent QC procedures.

- *Testing personnel*—Well-trained, proficient testing personnel are essential for quality test performance.

May I use data from the test system's manufacturer to establish an equivalent QC procedure?

No. Although manufacturers may assist laboratories by providing quality control instructions, the laboratory is ultimately responsible for the establishment, performance, documentation and evaluation of its quality control procedures, which take into account the laboratory's particular testing environment and personnel.

EQUIVALENT QC EVALUATION PROCESS

(not included)

MONITORING EQUIVALENT QC PROCEDURES

What do I do if an internal or external control result is unacceptable after I have implemented the equivalent QC procedure? May I continue reporting patient test results?

If any internal or external control result is unacceptable, the laboratory must re-test the unacceptable control one time. If the repeat result is acceptable, no further corrective action is necessary. If the repeat control result is unacceptable, the laboratory must identify the problem and take appropriate corrective action before reporting patient test results. This includes evaluating all patient test results obtained in the unacceptable test run and since the last run with both internal and external acceptable QC to determine if the results were adversely affected, before reporting the results and/or issuing corrected reports, if necessary. The laboratory must repeat and successfully complete the evaluation process before again reducing the frequency of testing external controls.

Are there any other quality monitoring activities I have to perform?

The laboratory must continue to perform the following on-going assessments:

- Quality assessment activities
- Proficiency testing
- Analytic system quality assessment
- Personnel competency assessments
- Calibration verification

What do I do if one of the on-going assessment indicators fails?

If unacceptable results are obtained for any of the above assessment activities, the laboratory must discontinue using the equivalent QC procedure, investigate, identify the problem, and document the actions taken to correct the problem. The evaluation process will have to be repeated and successfully completed before the laboratory may resume using the equivalent QC procedure.

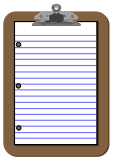
REMINDER: Even though the laboratory has implemented an equivalent QC procedure, it is still responsible for testing external control materials with each complete change of reagents, with each new lot number or shipment of reagents, following major preventive maintenance, or following replacement of critical parts that may influence the test system's test performance.

Where can I find additional information about CLIA requirement pertaining to equivalent QC?

You may refer to the State Operations Manual, Appendix C—Interpretive Guidelines, §493.1256(d), available on the CMS web site at: www.cms.hhs.gov/clia

TABLES

(not included)



CLIA BITS

ADDITIONAL WAIVED TESTS:

° Roche Diagnostics CoaguChek XS

° Medi-Lab Performance Infectious Mononucleosis (whole blood), H. pylori and Strep A Test-Twist

° Clearview MONO Whole Blood and Mono Cassette

° Signify Mono Whole Blood

° PerMaxim RediScreen Strep A Twist Cassette

° Cholestech LDX (Lipid Profile-ALT)

° Immunostics Detector H. pylori WB

° Immuno Detector Mono (whole blood)

° Cardinal Health SP Brand Rapid Test H. pylori (whole blood) and Rapid Test Strep A Dipstick

° Innovacon Multi-Clin Drug Screen Test Device

° Jant Pharmacal Accutest MultiDrug ER11 Drug Screen Test Device

° Arkray SPOTCHEM EZ Chemistry Analyzer (creatinine – whole blood) and Spotchem II Basicpanel 1

° Fisher Healthcare Sure-Vue H. pylori Test

° Select Medical Products Brand Rapid Test Strep A Dipstick and Twist, H. pylori

° Alfa Scientific Designs, Inc. Instant View Multi-Drug of Abuse Urine Test, Verdict Multi-Drug of Abuse Urine Test, Multi- Urine and Urine Cup Tests, Instant-Verdict Multi-Drug of Abuse Urine Cup Test and Instant-View Multi-Drug of Abuse Urine Cup Test

° eScreen, Inc. mCheck Multi-Line Screen Test Device

° Henry Schein One Step+ Mono

° Poly Stat Mono Test (whole blood)

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States in Region VIII (including Utah) are seeing an increase in fraudulent CLIA applications. Sometimes the “paper” lab chooses an address belonging to an existing laboratory. They use a fictitious name and director. A newer scheme involves using a known pathologist as the director with an address in a business office complex. One entity went so far as to submit the Director’s CV prepared by a web based organization. The director’s signature was forged and much of the CV information was false. The operations are billing scams well known on the West Coast.

Utah surveyors will be contacting lab directors more frequently to check on the validity of new site applications. Thank you for your patience and help in this matter.

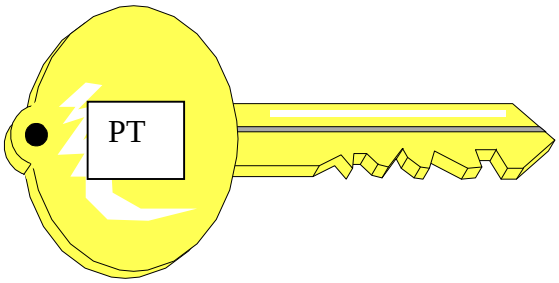
Equals

“365.25 days of drinking low-calorie beer because it’s less filling: 1 lite year”

Quality Assessment Spotlight

As soon as the laboratory received the first proficiency test (PT) score of 60% for hemoglobin, they immediately stopped reporting hemoglobin results to the clinicians until they could discover the problem. The lab manager had the manufacturer send a representative to service the instrument. The instrument seemed to be working just fine. They participated in the next event and also received a 60% score. With two consecutive failures, the lab received a letter from CLIA. After consultation with the CLIA office, the manager determined their results were being graded against all methods as there were not enough labs enrolled with that PT provider to be "peer" graded (same instrument, reagent combination). The lab changed PT companies and passed the next two events.

Kudos Julie Bennett, Lab Manager, Pulmonary Internal Medicine



Defining proficiency testing terms used in agency evaluation forms may be of some help to you in recognizing problems before they become significant.

Accuracy = your answer is close to the "true" value
Bias = your results are always higher (or lower) than the reference or standard value
Coefficient of Variation (%CV) = a result's standard deviation from the mean divided by the mean times 100 (evaluates precision)
Coefficient of Variation Index (CVI) = the lab' CV% divided by the median peer CV (compares your variation to that of your peers)
Mean = the average (add up all results and divide by the total number of entries)
Median = middle (the exact midpoint between the highest and lowest value)
Mode = most frequent answer
Outlier = an extremely high or low value when most results cluster together
Precision = achieving nearly identical results when testing the same sample many times
Random Error = something that alters a single result or that day's results – reagent problem (not mixed well, not warmed sufficiently), unstable temperature, unstable electrical supply, operator variation, faulty pipet, inadequate timing, etc. [NOTE: random error does not mean "we do not know what happened so there is no problem"!]
Range = the lowest to highest value reported
Standard Deviation (SD) = the calculation of the spread of individual data points above and below the mean (another precision evaluator)
Standard Deviation Index (SDI) = lab mean minus the average peer mean divided by the peer SD (accuracy evaluation)
Systemic Error = some change / problem affecting all results all the time – reagent lot change, wrong calibrator value used, reagents deteriorated, instrument part malfunctioning, etc.
Total Error = method's analytic error calculated by one of two complex methods (useful in assessing inaccuracy, imprecision, random or systematic error)
Z-Score = a result minus the mean of all labs divided by the SD of all results

Cautions:

Use your extra proficiency test materials as "blind" samples to check employee competency only after the cut off date for submission to the provider (no suspicion of cheating to get good results).

Watch the results you submit. For white blood cell differentials, does the company want the total number of each cell type or do they want the %? If someone else checks the results before you send in the report, does someone else check (verify) patient results before you report them?

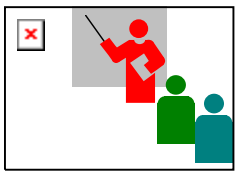
SAFETY

Have someone who does not work in your lab do a walk through to spot safety problems you fail to notice because you are used to the way things are done. This person could be from another lab, or even a clerical employee who seldom goes in your laboratory. Utah OSHA training section will do a complimentary walk through, but they have limited laboratory experience. Maybe both types of self inspection would be helpful.

Ponderables:

When you are in Heaven, do you get stuck wearing the clothes you were buried in for eternity?

CONTINUING EDUCATION



NLTN

"Biosafety and Biosecurity for Research Labs" Boston, MS November 1-2, 2007.
www.nltn.org

"Podcast and Virtual Unknown: 2007 Antimicrobial Susceptibility Testing Series by Janet Hindler, MCLS, MT(ASCP), F(AAM)
www.nltn.org/astpodcast.htm

Check their website for countless educational opportunities.

Understanding Our Universe

"Only two things are infinite, the universe and human stupidity, and I'm not sure about the former."

Albert Einstein